



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|-----------------------------|
| 10/825,127 | 04/16/2004 | Naoyuki Fukuchi | 251865US0CONT | 7991 |
| 22850 7590 08/27/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER GABEL, GAIENE | |
| | | | ART UNIT 1641 | PAPER NUMBER |
| | | | NOTIFICATION DATE 08/27/2008 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/825,127 | Applicant(s) FUKUCHI ET AL. | |
| | Examiner GAILENE R. GABEL | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-31 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) 21-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 and 35-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2008 has been entered.

Amendment Entry

2. Applicant's amendment and response, filed July 22, 2008 is acknowledged and has been entered. Claims 36-39 have been added. Claims 21-30 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 21-31 and 35-39 are pending and are under examination.

Withdrawn Rejections

3. All rejections not reiterated herein, have been withdrawn.

Art Unit: 1641

4. In light of Applicant's submission of Certified Translation of foreign priority applications, the rejection of claim 31 under 35 U.S.C. 103(a) as being unpatentable over Lopez et al. (Cloning of the alpha chain of human platelet glycoprotein Ib: a transmembrane. Proc. Natl. Acad. Sci. USA 84: 5615-5619 (December 28, 1987)) in light of Ruggeri et al. (WO 93/16712), in view of Simonet et al. (US 6,790,823), is hereby, withdrawn.

5. In light of Applicant's submission of Certified Translation of foreign priority applications, the rejection of claim 35 under 35 U.S.C. 103(a) as being unpatentable over Lopez et al. (Proc. Natl. Acad. Sci. USA 84: 5615-5619 (December 28, 1987)) in view of Simonet et al. (US 6,790,823) and in further view of Foster et al. (US Patent 4,444,879), is hereby, withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 1641

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 31 and 35-39 are rejected on the ground of nonstatutory double patenting over claims 12-14 of U. S. Patent No. 6,878,811 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a chimeric protein and a kit comprising the chimeric protein which consists of an Fc region of immunoglobulin molecule fused at its amino terminus to a partial protein of glycoprotein Ib α chain at its carboxyl terminus, wherein the partial proteins consists of amino acid residues 1-319 of GPIb α , or amino acid residues 1-293 of GPIb α , or amino acid residues 251-285 of GPIb α , all of which consist of the von Willebrand binding site of GPIb α .

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Double Patenting

7. Claims 31 and 35-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-14 of U.S. Patent No.

Art Unit: 1641

6,878,811 in view of Lopez et al. (Cloning of the alpha chain of human platelet glycoprotein Ib: a transmembrane. Proc. Natl. Acad. Sci. USA 84: 5615-5619 (December 28, 1987)) or Ruggeri et al. (WO 93/16712). Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions recite a chimeric protein and a kit comprising the chimeric protein which consists of an Fc region of immunoglobulin molecule fused at its amino terminus to a partial protein of glycoprotein Ib α chain at its carboxyl terminus, wherein the partial proteins consists of amino acid residues 1-319 of GPIb α , or amino acid residues 1-293 of GPIb α , or amino acid residues 251-285 of GPIb α , all of which consist of the von Willebrand binding site of GPIb α .

US Patent 6,878,811 differs in failing to recite that the partial protein consists of amino acid residues 1-319 of GPIb α , amino acid residues 1-293 of GPIb α , and amino acid residues 251-285 of GPIb α .

Lopez et al. teach a partial protein which consists of amino acid residues 1-319 of human glycoprotein Ib chain. According to Lopez et al., the partial protein contains therein the von Willebrand factor binding site of glycoprotein Ib α chain (Abstract, p. 5615, 1st and 2nd col., and Figure 2).

Ruggeri et al. disclose antithrombotic polypeptides based upon partial proteins (fragments) of glycoprotein Ib α (GPIb α). In as far as the actual binding site for vWF, Ruggeri et al. specifically provide that the actual binding site for vWF on GPIb-IX receptor is localized within and consists of the region of GPIb α chain comprising amino acid 1-293 residues of the GPIb α chain. The polypeptides are modified and patterned

Art Unit: 1641

on fragments of GPIIb α that comprise all or part of the binding domain of GPIIb α for von Willebrand Factor (vWF). See page 9, lines 3-24; page 12, lines 24-31; page 13, lines 15-39; and page 16, lines 15-19.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to specifically design the partial protein of GPIIb α to consist of any one of amino acid residues 1-319 of GPIIb α , amino acid residues 1-293 of GPIIb α , or amino acid residues 251-285 of GPIIb α for incorporation with the Fc region of an immunoglobulin for binding with vWF because both Lopez and Ruggieri specifically taught that amino acid residues 1-319, 1-293, or 251-285 contain the binding site for vWF. It also would have been obvious to incorporate the chimeric protein into a kit format for detecting binding of VWF, because kits are well known and conventional in the art for their recognized advantage of convenience and economy.

Response to Arguments

8. Applicant's arguments with respect to claims 31 and 35 have been considered but are moot in view of the new grounds of rejection.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAIENE R. GABEL whose telephone number is

Art Unit: 1641

(571)272-0820. The examiner can normally be reached on Monday to Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

August 21, 2008